

III. REMARKS

Applicants wish to draw the Examiner's attention to the attached Supplemental IDS and corresponding reference, WO 03/028730.

Claim Amendments

Claims 1, 6, 9-10 and 12-13 are pending. Claims 2-5, 7-8 and 11 have been cancelled without prejudice. Claims 1, 6, 10, 12 and 13 have been amended to further point out and clarify the invention.

Claims 1, 10, 12 and 13 were amended to specify the PDE5 inhibitor sildenafil or a pharmaceutically acceptable salt thereof, and the angiotensin receptor II antagonists olmesartan, olmesartan medoxomil, and pharmaceutically acceptable salts thereof, support for which can be found on page 10, lines 4-9 and lines 22-23.

Claim 6 has been amended to reflect the antecedent sildenafil in claim 1.

Objection to the Oath/Declaration

On page 2 of the Office Action, the Oath/Declaration was objected to as not complying with the requirements of 37 C.F.R. 1.63(c) for failing to reference the foreign application and for failing to identify the city/state/country of residence of each inventor.

Applicants submit a new oath/declaration with reference to the foreign application and with each inventor's residence. Therefore, Applicants request that the objection be withdrawn.

Objection to the Title

On page 3 of the Office Action, the amendments to the Title made in the Response dated June 9, 2005 were objected to as not being consistent with the remarks section. Applicants have amended the title as suggested to ---Pharmaceutical Combinations Comprising a PDE5 Inhibitor and an Angiotensin II Receptor Antagonist for the Treatment of Hypertension---. Therefore, Applicants request that the objection be withdrawn.

Rejection under 35 U.S.C. § 132(a)

On page 4 of the Office Action, the Office objects to the amendments to the specification filed on June 9, 2005 and requires Applicant to cancel the new matter. The amendments to the specification have been cancelled in the amendments to the specification recited above. A statement under 35 C.F.R. § 1.17(f) is attached. Therefore, Applicants request that the rejection be withdrawn.

Rejection under 35 U.S.C. § 102(b)

On pages 4-7 of the Office Action, the Office rejected claims 1-5, 7, 9-11 and 13 under 35 U.S.C. § 102(b) as being anticipated by Macor *et al.* (U.S. Patent No. 6,087,368; 2000).

Applicants have cancelled claims 2-5, and 7. Claims 1, 6, 10 and 12 have been amended to specify the use of sildenafil and a pharmaceutically acceptable salt thereof and olmesartan or olmesartan medoximil and pharmaceutically acceptable salts thereof. Applicants submit that *Macor et al.* does not teach any of the above in combination for the palliative treatment of hypertension, including essential hypertension, pulmonary hypertension, secondary hypertension, isolated systolic hypertension, hypertension associated with atherosclerosis and renovascular hypertension, congestive heart failure, angina, stroke, diabetes and impaired glucose tolerance. Therefore, Applicants request that the rejection be withdrawn.

Rejection under 35 U.S.C. § 103(a)

On pages 8-15 of the Office Action, the Office rejected claims 1-13 as being obvious over of *Macor et al.* in view of The Merck Manual of Diagnosis and Therapy (16th Edition; 1992, p. 413-431), Cecil's Textbook of Medicine (Twenty-First Edition, 2000, 273-279 and 1279-1285), and Physician's Desk Reference (55th Edition, 2001; p. 323 and 330). Applicants submit that *Macor* does not broadly disclose the use of any cGMP PDE5 inhibitor in combination with any angiotensin II antagonist for the treatment of cGMP-associated conditions as described by the Office. Rather, *Macor* discloses the use of the specific compounds disclosed in combination with angiotensin II antagonists. There is no teaching or suggestion in *Macor* that PDE5 inhibitors as a class would work in combination with angiotensin II antagonists as a class. Further, there is no teaching or suggestion pointing to the specific combination of sildenafil and olmesartan, out of a very large genus of potential PDE5 inhibitors and angiotensin II antagonists, in any of the references cited by the Office. Therefore, Applicants submit that the Office has failed to make a *prima facie* showing of obviousness, and request that the rejection be withdrawn.

It is therefore submitted that Claims 1, 6, 9-10 and 12-13 are in condition for allowance. If the Office has any further comments or concerns, the Examiner is welcome to contact Applicants at the number below.

Respectfully submitted,



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